K010598

MAR 2 3 2001

Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278-1205

TEL (800) 624-8380 or (310) 536-0006
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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is:_____

Proprietary Name:	Synovialscopics
Common Name:	Synovial fluid control
Classification Name:	Hematology Quality Control Mixture
Medical specialty:	Hematology
Product Code:	JPK
Device class:	2
Regulation No:	864.8625
Manufacturer:	Quantimetrix Corporation 2005 Manhattan Beach Boulevard Redondo Beach CA 90278 Phone: 310/536-0006 FAX: 310/536-9977
Contact Persons:	Eva Laszlo, Manager, QA/QC, 310-536-0006x134
Registration No:	2020715
Establishment:	Quantimetrix Corporation 2005 Manhattan Beach Boulevard Redondo Beach CA 90278 Phone: 310/536-0006 FAX: 310/536-9977

The Quantimetrix Synovialscopics control is supplied liquid in an eyedropper bottle. It consists of a human source matrix to which preservatives, crystals and human red and white blood cells (at different concentrations) have been added to achieve two distinct levels.

Counts for the red and white blood cells were obtained from interlaboratory data.

The Quantimetrix Synovialscopics is substantially equivalent to the currently marketed **Spinalscopics** *spinal fluid control* manufactured by **Quantimetrix Corp.**

Both feature similar matrices, constituents and stability claims.
The Quantimetrix Synovialscopics is supplied in two levels with differing cell counts and different crystals (Type A and Type B), 1.5 ml each level per box.

Intended Use

The Quantimetrix Synovialscopics Synovial Fluid Control is intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient synovial fluid samples and to aid in identification of crystals which may be present in synovial fluid under certain pathological conditions. Controls with known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method.

Performance Characteristics

Accelerated stability studies (25°C and 37°C) were performed on multiple lots of control to predict the shelf life at 2-8°C. Based on those studies the shelf life was predicted to be at least 1 year when stored refrigerated.
Real time studies are ongoing at 2-8°C to determine the actual shelf life of the control material.

Multiple lots of the control were found to be stable for at least 75 days at 25°C.

Opened and closed storage of the Synovialscopics control was studied and no significant difference was found.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 3 2001

Ms. Eva Laszlo
QA/QC Manager
Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, California 90278-1205

Re: K010598
Trade Name: Synovialscopics, Synovial Fluid Control
Regulatory Class: II
Product Code: JPK
Dated: February 26, 2001
Received: February 28, 2001

Dear Ms. Laszlo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K010598

Device Name: Synovialscopics

Synovial Fluid Control

Indications For Use:

The Quantimetrix Synovialscopics Synovial Fluid Control is intended for monitoring total cell counts performed manually using a hemocytometer to validate quantitation of red and white blood cells in patient synovial fluid samples and to aid in the identification of crystals which may be present in synovial fluid under certain pathological conditions. Control materials with known component concentrations are an integral part of diagnostic procedures. Daily monitoring of control values establishes intralaboratory parameters for accuracy and precision of the test method.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010598

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR **Over-The-Counter Use**_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)